Bandage Stabilizer

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Abstract

To treat severe wounds, burns, and other cases in which serious injuries have caused damage to the body's peripheral tissue, skin grafting is utilized. The most successful and commonly used skin graft is the split thickness skin graft. The typical donor site for these skin grafts is the upper leg because the incisions and scars made during the surgical procedure are readily concealed [6]. Dressings are applied over the recipient and the donor wound sites. In order to provide additional stability to the donor site dressing, ACE bandages are currently used in the hospital industry. However, ACE bandages prove to be ineffective because they commonly slip off the application site. Therefore, the design team has developed three designs in order to solve this dilemma. Three possible solutions utilize compression shorts, slip guard, and the elastic leg wrap, respectively. Through an exhaustive analysis of the positive and detrimental attributes of each design, the elastic leg wrap was deemed the best solution to the problem. After three initial prototypes, a final device was fabricated that satisfied all of the client's primary requirements.

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Design Motivation

The overall motivation behind this project is to create a bandage stabilizing device to be utilized on the upper thigh. Skin grafts are most commonly extracted from the upper thigh. During the healing process, dressings are applied to the site of the open wound. To minimize the amount of time it takes to heal and minimize infection it is necessary for these dressings to have minimal movement across the wound. Currently these dressings are held in place by ACE bandages but patients have a difficult time keeping these bandages in place as they oftentimes slip down the leg. As a result, the dressings experience movement in turn as they are not held in place with adequate pressure. The design team's goal is to create a device that can take the place of ACE bandages to apply sufficient pressure to the wound without moving down the leg.

Client Information

Our Client is Dr. Michael Bentz, who currently is a professor of surgery at the University of Wisconsin School of Medicine and Public health and is also the chairman of the Division of Plastic and Reconstructive Surgery.

Problem Statement

The client, Michael Bentz, MD, has requested a device to replace the current elastic bandage used to hold dressings in place on post-operative patients. Current methods for maintaining the dressing's position are ineffective since the current bandage typically slides out of place during the course of the healing process. The primary location of use for the device is around the upper leg. Additional areas of application can include the lower leg, the upper arm, and the lower arm.

Background

Skin grafting involves transplantation of skin from one area of the body to another in order to treat serious injuries to the skin such as lacerations or extensive burns. Benefits of skin grafting include reduction in the required treatment time and improvement in function as well as appearance of the recipient site. The type of skin graft that is considered to be the most durable and has the broadest range of application is the split thickness skin graft [6].

Split thickness skin grafting involves a standardized protocol established and practiced by surgeons. In order to remove the donor skin site, an instrument called a dermatome (Figure 1) is used to produce a split thickness skin graft. A split thickness skin graft contains the epidermis and a portion of the dermis [5]. After removal of the skin graft from the donor site, the donor location still contains a dermal layer that contains hair follicles and sebaceous glands. These dermal structures are important to retain because hair follicles and sebaceous glands contain epidermal cells that rejuvenate a new layer of epidermis.

Figure 1: A surgical dermatome [5].

In order to prevent buildup of edema under the graft, a phenomenon that causes complications in revascularization and reattachment of the skin graft, the graft may be meshed

by making lengthwise rows of cuts a few millimeters long. This process helps to allow the graft to stretch and cover a larger surface area. The implication of this is that the amount of donor skin needed is reduced. In current practice, two different methods of meshing exist. One method includes utilization of a smooth plastic plate to guide the skin graft under circular notched blades (Figure 2). The other method utilizes two opposing rollers to cut the skin graft as the two rollers meet. This is analogous to a scissor's blades cutting paper [6].

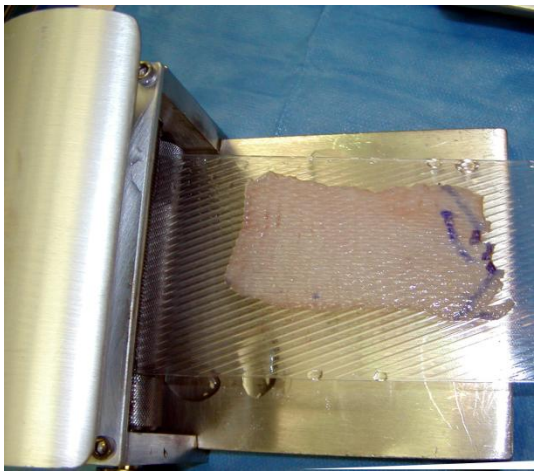


Figure 2: A skin graft undergoing meshing [5].

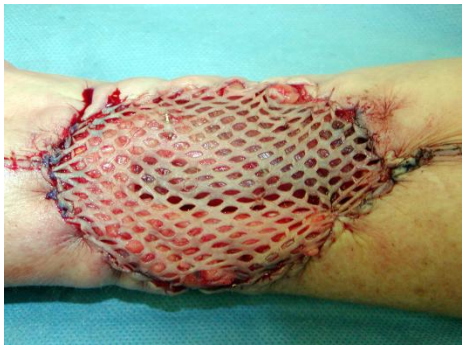


Figure 3: A split thickness skin graft that underwent meshing followed by securing to the recipient site [5].

After all the processing of the skin graft has been completed, the graft is then applied to the recipient site. To secure the skin grafts in the proper position, a few stitches or surgical staples are used (Figure 3). The graft receives nourishment from the dermal capillaries in the wound until revascularization of the graft occurs. The time period from implantation of the graft on the recipient site to vascularization is approximately 2 to 3 days. This phase is typically called the plasmatic imbibition phase in which the graft "drinks plasma" [4].

After the skin graft has been secured to the recipient site, a final dressing is applied to the recipient location in order to prevent shearing forces, seroma, or hematoma formation between the skin graft and the contacting recipient site. Two different types of dressing exist in order to accomplish this goal [6]. One is the bolster dressing and the other is the negative pressure dressing (Figure 4). A bolster dressing is composed of wrapping moistened cotton balls in petroleum gauze. It is secured to the site by placing sutures radially around the wound and tying them over the dressing [5]. A negative pressure dressing utilizes a foam filler dressing, a drape, and vacuum source to create a negative pressure relative to the atmosphere to the wound environment [2].

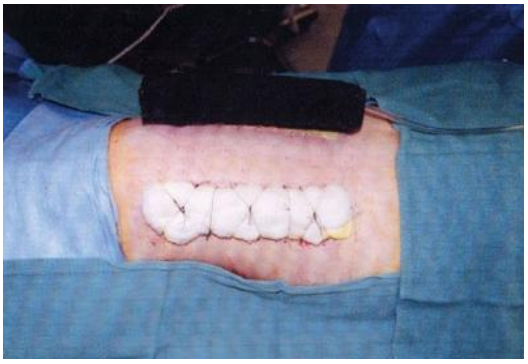


Figure 4: Bolster dressing shown on the bottom and the negative pressure dressing shown on top [3].

In addition, in order to reduce pain and to improve healing time by providing a moist environment, dressings are also applied to the donor site. The most common donor site is the upper leg due to its inconspicuous location. Surgeons often use occlusive polyurethane to dress the wound. To further provide stabilization to the dressings, the doctors use ace bandages to wrap the donor site, providing uniform pressure [6]. However, this method does not stay in place securely to the site and commonly falls off, increasing recovery time for patients.

Current Practices

The current means of securing post-operational dressings is by applying an ACE bandage over the dressings. These ACE bandages need to be wrapped around the leg numerous times to fully cover the area of concern and to create the necessary pressure. However, these multiple wrappings add weight and cause the bandage to become bulky. Consequently, it is very common for the bandage to slip down the leg. To counteract this, adhesive tapes and glue-like substances can be applied to help maintain the bandages' position, but these measures can be painful and messy upon removal. Patients often find other creative ways to keep the bandages in place. Examples of this include wrapping the bandage around the waste or using a garter belt; however, none of these methods are very successful or convenient.

Requirements and Design Constraints

There are a number of primary specifications and requirements the design must meet. First, the device must hold dressings in place without sliding down the leg. This is crucial to ensure proper healing of the wound. The typical patient will not be doing extensive exercise or movement after surgery; however, this device should be able to work adequately in the rare situations of vigorous movement.

Furthermore this device must be easily applied by the patient without help. This device will be utilized in most cases while the patient is recovering while at home and some patients may also be bed-ridden. It is important for this device to not make a patient dependent on others while going through the recovery process. Therefore the design must be simple and easily attachable.

It is important for this device not to create further problems for the patient. This means that the device cannot cause a tourniquet effect, which can be observed by the leg turning blue or the foot swelling. As a general rule of thumb, the device should be loose enough to be able to force two fingers between the device and the leg. Also, the patients will be in an uncomfortable state due to the recent surgery and it is important not to add to their discomfort. For this reason the device should not cause chaffing or rashes at the site of use. It is important to use hypoallergenic materials to avoid allergic reactions, which may exacerbate a patient's suffering.

Once these primary concerns are addressed there are several secondary issues the device should address given enough time and resources. First it would be ideal for the device to be aesthetically pleasing and customizable. This is both for marketing purposes and as a means of increasing the likelihood of pediatric patients using this device without complaint. This device's design could also be greatly improved if it were machine washable. A patient could be given two devices and while wearing one, wash the other. Making the device machine washable would increase the usability and convenience of the design.

Lastly, it would be ideal if this device could be applicable in a wide variety of areas. For instance, this device could be efficacious for maladies other than skin grafts simply by applying it to injuries dealing with the lower leg, upper arm, and lower arm. If this device could be used in these areas it would greatly increase the marketability and versatility of the product. Furthermore it would be useful if this device could be utilized within veterinary medicine. Veterinarians have a problem keeping bandages on animals after surgery, which increases the likelihood of infection and increases the recovery time for the animal. This device could be of use in these situations.

Proposed Designs

I. Compression Shorts

The utilization of the compression shorts design is similar to simply wearing a pair of shorts. Limiting the need for any type of wrap, adhesive, or tape, the compression shorts would, ideally, replace the current ace wrap method and have the potential for multiple uses. To eliminate any complications that would result from sliding the shorts up the users leg, the design includes a "breakaway" system. The "breakaway" system, which gives the ability for placement while a patient is either unconscious or simply unable, is created by implementing a zipper on the inner thigh of the shorts as well as down one of the sides (Figure 5); thus, allowing for the shorts to be either slipped underneath or wrapped around and then zipped up. Painful and ergonomically unsound, the necessity of having to pull the shorts over the wound site (as a typical pair of shorts would be put on) becomes inessential.

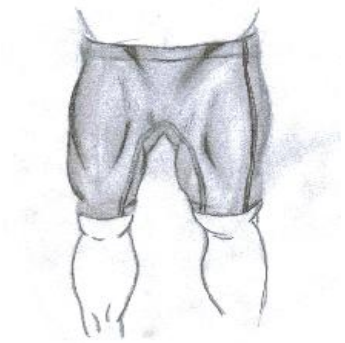


Figure 5: Compression shorts design with zippers on the side and crotch.

The compression shorts design would effectively take advantage of the elastic properties of nylon. Composed primarily of nylon and polyester, the compression shorts are a comfortable, breathable, and simple design. A primary characteristic of the compression shorts is the material of which it is made. Nylon has important properties that make its utilization exceptional for this design. In terms of durability it has a tensile strength higher than those of cotton, wool, silk, and rayon. This tensile strength can mostly be attributed to the intrinsic elastic nature of nylon, which can be described as 100% elastic under 8% stretch [1]. The elasticity of nylon fulfills the specification of creating pressure around the wound without the deleterious tourniquet effect.

II. Slip Guard

The basic premise of the slip guard is the ability for attachment without special elastic materials, adhesives, or other forms of stabilization. Supported by the natural landmark of the knee, the slip guard would simply rest on the user's leg and provide a base for the already implemented ace bandage (Figure 6). Because of the assumption that the knee can be utilized as an appropriate site for support, the primary materials would be selected based on an assessment of cost and comfort rather than ability of effectiveness and utilization.

Figure 6: Displays the set up of the slip guard stabilizing an ace bandage wrap.

Statistical Assessment of Slip Guard Design

The Slip Guard design is based on the assumption that the leg contains some genre of projection to allow for the device to rest comfortably on the landmark. For proper utilization, however, proper statistical analysis of this assumption is essential. Testing was done by following the data analysis guidelines and standardizations table attached in the appendix. Analysis consisted of the measurement of the circumference of the thigh in increments of 5 cm down the leg starting from a straight line drawn across the leg from beginning of the crotch to the top of the patella. Measurements of the length of the femoral region along with overall height and weight were also taken. The population tested consisted of seven females and fourteen males (unequal populations of the sexes is due to differing levels of willingness to participate).

Preliminary analysis of the data was performed by graphing the circumference of each leg relative to the numbered marking associated with the measurement. Each of these graphs were evaluated and it was determined that an average of all graphs was sufficient for looking at the overall shape of the curve (Graph 1). This graph illustrates that a linear regression model can be initially assumed, as shown by the acceptable coefficient of determination. While this curve does show a generalized function for the conic shape of the leg, further analysis was done to create a more universal definition.

In-depth analysis was done by viewing the data in terms of percent (%) change from initial measurement to the measurement in question. This methodology allowed for a more standardized analysis of data. From inspection and the given R-squared value it can be implied that a function of the conicality of the leg lies somewhere between a 3^{rd} degree polynomial (Graph 2) and a linear regression (Graph 3). Table 1 and Table 2 reiterate this assumption. Table 1 displays the average change in circumference for each measurement in terms of what percent the allocated measurement was of the initial measurement. For instance, measurement 2, which was taken 5 cm from the measurement 1 (the initial measurement), is 95.956 ± 0.0085 % of the initial measurement. It should be noted that the final measurement, as seen in the final row and final column of Table 1, is not applicable due to lack of measurements for this location of the leg.

At this time, further analysis as well as further data collection needs to be performed to properly define the conicality of the leg as a function. This fact can be seen in Table 2, which depicts the information in table 1 in terms of percent change of a measurement compared to the previous measurement. The 95% confidence interval for this data set is not sufficient to conclude a linear relationship.

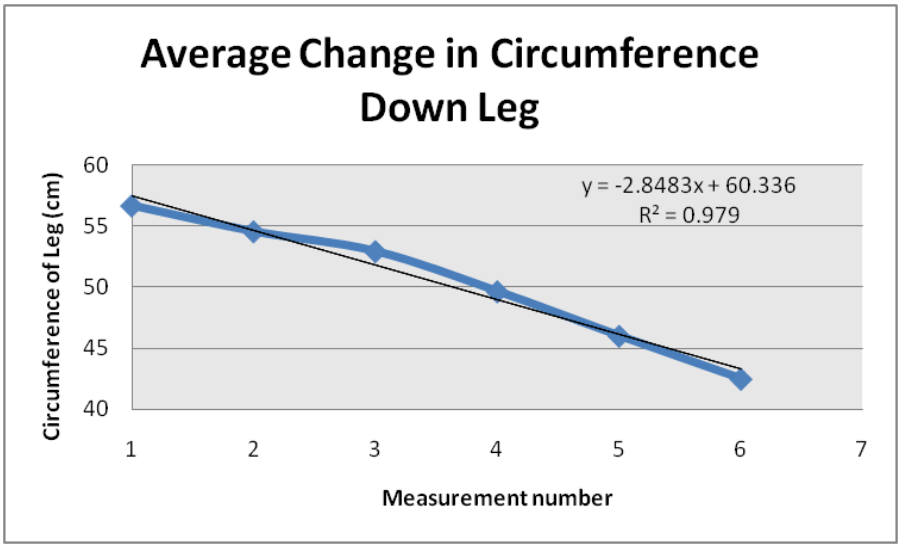
In essence these statistics can be utilized in two ways. Primarily they show that no protuberance is in existence at any point down the femoral region of the leg to the patella. This conclusion, in itself, makes the mentioned above slip guard ineffective. This statistical analysis can also be used for future work of this design in terms of creating different sizes.

Measurement	Distance Down Leg (cm)	Average % of Initial	95% Confidence (%)	95% Confidence (cm)
1	0	100	0	0
2	5	95.956	±0.0085	56.643 ± 0.0048
3	10	92.74	±0.012	54.53 ± 0.0046
4	15	86.64	±0.020	52.91 ± 0.0049
5	20	79.86	±0.026	49.63 ± 0.0042
6	25	74.31	±0.021	45.99 ± 0.0039
7	30	69.27	±0.019	42.48 ± 0.0036
8	35	66.8	±0.026	N/A

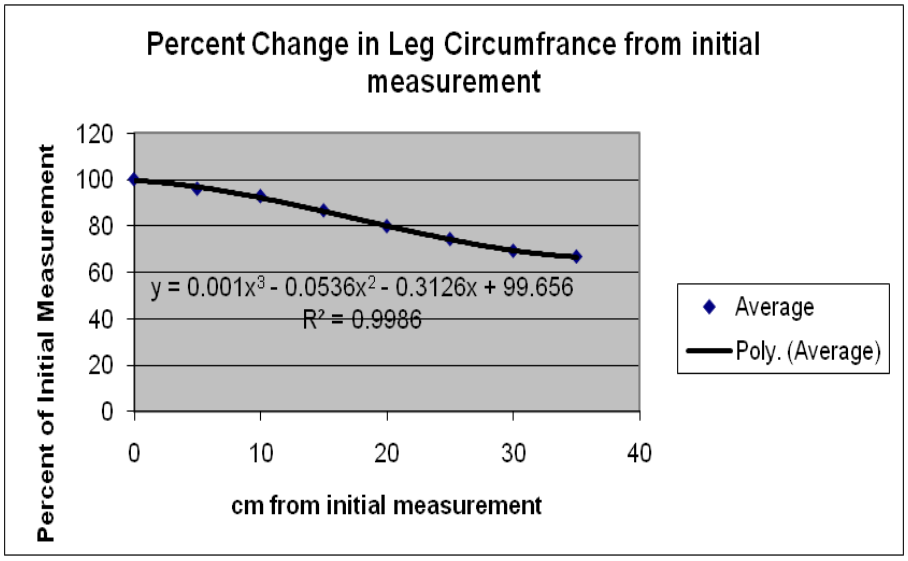
Table 1: Displays the average change in circumference for each measurement in terms of its' percentage of the initial measurement.

Measurement	Average % Change From Previous
1	N/A
2	4.044
3	3.216
4	6.1
5	6.78
6	5.55
7	5.04
8	2.47
Overall Average With 95% CI	4.743 ± 1.24 %

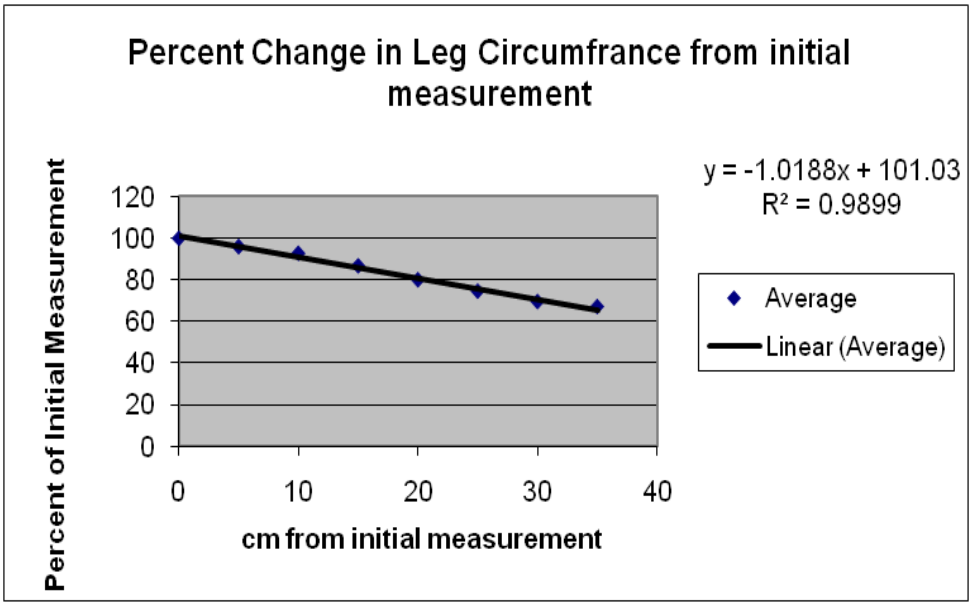
Table 2: Depicts the average percent change of each measurement in terms of how it relates to the previous measurement taken.



Graph 1: Displays the average circumference of the leg with each measurement.



Graph 2: Displays the 3rd degree polynomial of the average percent change in terms of the percentage of the initial measurement



Graph 3: Displays the linear regression of the percentage change in terms of the percentage of the initial measurement.

III. Elastic Leg Wrap Design

The third and final design is called the Elastic Leg Wrap (Figure 7). The Elastic Leg Wrap is essentially a one piece elastic fabric made of either nylon or spandex/cotton fabric. The leg wrap will be wrapped over the existing dressing applied to the wound and will entirely replace the need for an ace bandage. The same design can be used for the upper and lower leg as well as the upper and lower arm. One size of this leg wrap will fit most consumers, but multiple sizes can be manufactured for optimal comfort and stability. Ideally the Elastic Leg Wrap will only go around the thigh approximately one and a half times in order to reduce discomfort, sweating, and too much pressure on the wound. Minimal need to wrap the leg will also result in a light weight, durable product, which will preferably be machine washable and disposable after the patient has fully recovered.

Figure 7: Elastic Leg

To make the Elastic Leg Wrap safe for all consumers the fabric it is made out of must be both hypoallergenic and easy to put on. In some instances, patients are bedridden after a skin graft or other surgery, so the leg wrap should be able to be placed on a patient with ease while lying in bed. The fabric of choice has not yet been fully determined, but the leg wrap will be made out of a mostly nylon, elastic fabric. The wrap must be elastic in order to apply appropriate pressure to the dressing and also to allow the leg wrap to stay in place on the leg without slipping down the leg and disturbing the wound dressing.

To assist in keeping the leg wrap from sliding down the leg due to the effects of gravity and the conic shape of the thigh, the design team is interested in creating a non-slip lining on the interior of the wrap. This lining will be made predominantly of small squares of rubber (Figure 8). This rubber will be latex free, and will not cover the area of the dressing. The idea behind the small rubber squares is to increase the static coefficient of friction against skin to prevent slipping. Considerations for the rubber lining include; making sure the rubber does not pinch the skin when stretched, having enough breathing room between squares so the leg does not perspire, and creating the right placement of the rubber to maximize the friction on the leg. In order to avoid any friction over the wound dressing the rubber will be localized to only one section of the leg wrap.

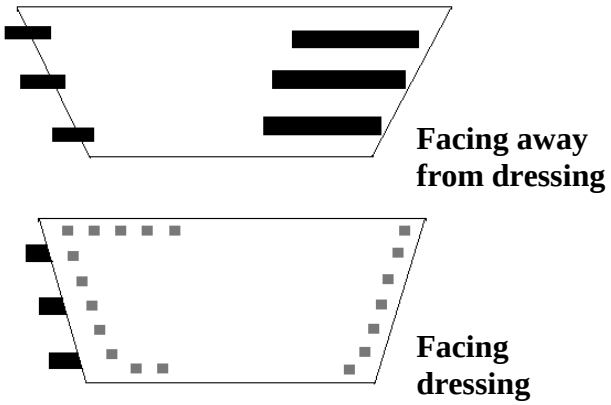


Figure 8: Diagram showing the adjustable Velcro on the outside and the rubber on the inside.

The leg wrap will be secured around the thigh by a series of plastic Dual Lock strips. Dual Lock is essentially Velcro, but instead of cloth it is made out of plastic. This makes it more durable and more secure. By adhering three strips to the outside of the leg wrap, the patient can easily adjust the pressure on the dressing and also the pressure on the leg to keep the apparatus from sliding off the desired area. On the leading edge of the wrap there will be three dual lock tabs that when wrapped around the leg will secure to the three strips. This securing system is

extremely durable and adjustable. The Dual Lock will not degrade if the patient decides to wash the wrap.

Design Matrix

Criteria		**Possible Designs**		
Considerations	Weight	Elastic Wrap	Compression Shorts	Slip Guard
Feasibility	20	19	16	5
Ease of Fabrication	10	9	6	9
Durability	10	8	8	9
Ergonomics	20	19	13	15
Safety	15	15	15	15
Adjustability	10	9	6	8
Client Preference	15	15	12	10
Total	100	94	76	71

Figure 9: Design matrix

This design matrix evaluates the three possible designs in seven different categories. Each category is weighted to give the designs an assigned score out of 100. As shown in Figure 9, the Elastic Leg Wrap outscores the other two designs by a considerable margin. The areas in which the leg wrap excelled are feasibility, ergonomics, adjustability, and client preference.

Feasibility combines the effectiveness of the design with an overall ranking of whether or not this product would be used by consumers. The leg wrap outscores the other two designs in this region because it will have a good chance of staying in place on the leg, as well as being easy to use and apply. The compression shorts will also stay on the dressing well, but will be more difficult to put on a patient and could potentially make daily activities more difficult. The leg wrap and the slip guard both scored high in the ease of fabrication. They both have fairly simple designs, whereas the compression shorts are more complex and would be harder to manufacture. The slip guard is considered to be the most durable of the three designs because it has the least amount of material, and would require the least maintenance. All of the designs scored well in the durability category because they would all be made out of similar durable fabric with no moving parts. The ergonomics category takes into account the ease of application and comfort level for the user. The leg wrap was considered to be the easiest to put on because it could easily be done by one person while lying down, and would be the most comfortable because it is localized to the donor site. All of the designs are safe and will not harm the user. In the adjustability category the leg wrap was rated the highest again because it can be wrapped as tightly or as loosely as desired, creating room for varying sizes of leg. The last category is client preference in which we asked our client which he preferred. He sided with the leg wrap due to

its comfort, ease of application, and ease of fabrication. The Elastic Leg Wrap clearly outscored the other two designs in the seven categories with which they were rated.

Final Design

The final design was established after preliminary testing of three initial prototypes. Features were taken from each of these prototypes to create the final product. This device utilizes an elastic fabric to apply pressure to the leg. It is lined with two strips of vinyl for additional friction upon the leg. The device is secured and tightened using four plastic clips. The device is further stabilized through an optional belt attachment. The belt attaches and tightens on the waste with the same plastic clip used for the device and adheres to the device with Velcro strips.

Picture 1: Photo of the final design

Fabrication

Once we decided on our final design, the logical next step was to begin fabrication. As with any project, fabrication often leads to the discovery of various design flaws. Because of this, it is important to begin fabrication as early as possible so that, by discovering many flaws, the design becomes progressively better. Each flaw might be viewed as a failure of an aspect of the design, and the more time spent during fabrication of a prototype the more prone these flaws are to being discovered. The flaws can then be fixed, leading to a better final device.

In order to begin fabrication, it was necessary to formulate a plan, get the necessary supplies, and gain access to the proper fabrication tools. It was decided early on that initially the most basic prototype possible should be created. This way, it was possible to test the concept of the design without spending very much time creating it.

The first basic prototype was created using 95% cotton, 5% spandex, black material, with a rubber interior. The rubber interior was very thin and added little to the stability of the bandage or the friction on the leg. The design was simple and required three Velcro straps, the male Velcro on the leading edge, and the female Velcro being sewn onto the fabric in nine inch strips. It was discovered early on the elastic material was difficult to feed through a sewing machine, as it stretched and often bound up in the gears with which fabric is fed past the needle. This effectively determined that only two thicknesses of elastic material were able to be fed through the machine at one time. Also, the female end of the Velcro which had adhesive on the side which attached to the material was very difficult to sew with a machine as the adhesive gummed up the needle causing it to stick in the fabric. This was remedied by coating the needle with soap every 50 approximately every 50 stitches to keep it from coating with adhesive.

Upon completion of the first prototype testing showed several glaring flaws. First, the top and bottom edge of the wrap would fold over, because the Velcro was not lined up on the top and bottom. Also, the most crucial flaw, the prototype did not stay on the leg as it was intended and quickly dropped down the leg.

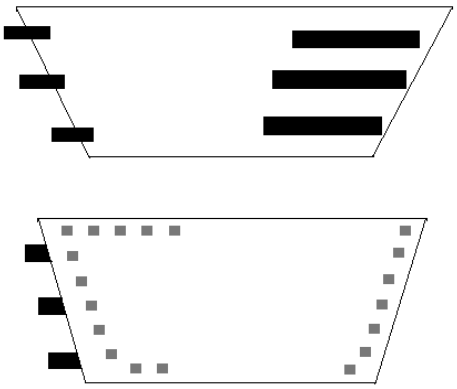


Figure 10: This shows the initial design for the first prototype, the solid black squares represent Velcro, and the grey represents rubber.

The second prototype had several different key elements. First, the material used was 94% cotton and 6% spandex, which drastically changed the elasticity of the fabric. Also, the second prototype was created to have 4 strips of Velcro instead of three. The female end up of the Velcro was cut into small squares, meaning the wrap would retain more elasticity throughout the Velcro area. This can be seen in the figure below. Aside from the change in material there were also three strips of non-slip rubber added to the interior, in an attempt to increase friction.

Figure 11: This shows the difference in placement of the Velcro and also the arcing dressing.

Testing of the second prototype showed that several of the problems from the first prototype were solved, however, the bandage still slipped down the leg much too quickly upon walking. One positive note from the second prototype was that the wrap was barely noticeable on the leg, and was found to be extremely comfortable.

With the creation of the third prototype a completely new material was found as well as an additional belt attachment made from elastic straps and a buckle. The material used for the wrap was a 4 inch wide strip of elastic, and the wrap was made from 3 of them sewn together in seems. This prototype also used dual lock instead of Velcro, which has to male or female end, only very small plastic hooks. The belt then attached to the wrap via a strip of the same elastic used to create the wrap. This prototype was found to be extremely elastic, and to compensate it was shrunk down two inches from the original design.

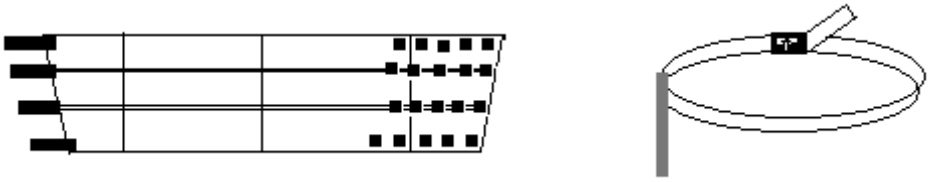


Figure 12: This shows the third prototype made of strips of elastic as well as the belt.

Upon testing the third prototype was found to be even more effective than the second prototype; however, it was extremely uncomfortable and hard to affix to the leg. It was found that when applying the belt attachment to the second prototype, the prototype did not slip down the leg.

This led to the creation of the final design. The final design was made from the same fabric as the second, except instead of Velcro it used four buckles similar to that of the belt. The leg wrap could then be buckled on and tightened via pulling the straps which ran through the buckle. Also, two strips of vinyl were added to the interior to increase friction on the skin. This design was much easier to fabricate than the other because it lacked the adhesive of the Velcro, and was easy to run through a sewing machine. Total fabrication time for this final prototype was under three hours, which included laying out the design and cutting all the fabric to size. The belt was still thought to be a necessary additional attachment, so two strips of Velcro were added to the exterior.

Figure 4: This shows the final design, including the plastic buckles.

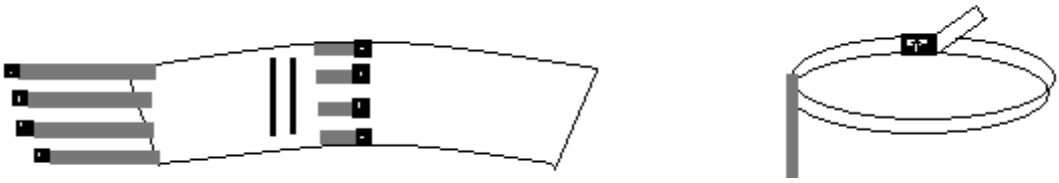


Figure 13: This shows the final design, including the plastic buckles.

Testing

Stress/Strain

To allow for comparison between the prototypes and the ACE bandage in testing, a proper procedure was followed in order to standardize the pressures. Three tensile test trials for each type of sample material- the ACE bandage, the spandex, and the elastic wrap- were performed using a MTS Sintech Universal Testing Machine (Figures 14, 15, & 16). Each sample's cross sectional area was measured using calipers. Each type of sample was then held in place using two inch wide clamp grips and the length between the cross was measured because this quantity defined the gauge length. The MTS Sintech Universal Testing Machine was interfaced with a laboratory data acquisition program called TestWorks 4. This software provided the load, time, and crosshead extension during the tests. From these values, stress vs strain plots were generated using Formula 1 & 2 (Figure 17). These curves were then fitted with

the best polynomial (Figures 18, 19, & 20). These polynomials gave stress as a function of strain. The polynomials for ACE bandage trail 1 and white elastic wrap trial 1 were not used in further calculations because the polynomial gave unreasonable answers such as a negative value for stress. These answers were erroneous because the tensile test that this data was obtained from was ended prematurely due to a time constraint during the day of testing. Two or three inch gauge marking via a permanent marker were then applied to the prototypes. This was done in the hoop direction for the elastic wrap prototype and the prototype made of spandex in an area away from any stress concentrations, such as stitch seams. Two inch gauge markings via a permanent marker were applied to the ACE bandage along the axis of the bandage. When the prototypes and the ACE bandage were applied to the upper leg, the gauge length elongated, and using Formula 2, the corresponding strain was found. The strain for the ACE bandage was then plugged into the two appropriate stresses as a function of strain (Figure 19) and the average of these stress values was obtained. The strain for the prototype made of the spandex was then plugged into the three appropriate stresses as a function of strain (Figure 20), and the average of these stress values was obtained. The strain for the elastic wrap was then plugged into the two appropriate stresses as a function of strain (Figure 21), and the average of these stress values was obtained. The average stress values were then plugged into Formula 3 or 6 to obtain the average pressure in psi (Figures 22 & 23). The psi was then converted to mmHg using Formula 7 (Figure I). The pressure for all the prototypes and the ACE bandages for each trial of walking to failure are noted in Figures 24, 25, & 26.

Figure 14: Tensile test performed using a MTS Sintech Universal Testing Machine on the ACE bandage.

Figure 15: Tensile test performed using a MTS Sintech Universal Testing Machine on the spandex material.

Figure16: Tensile test performed using a MTS Sintech Universal Testing Machine on the elastic wrap material.

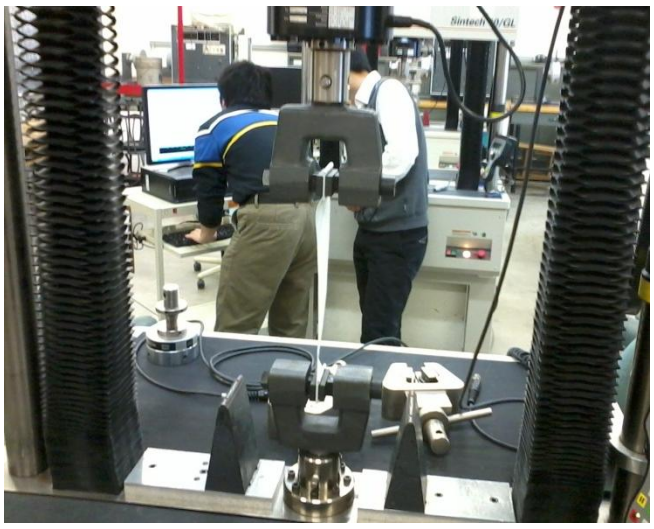


Figure 17: Formula to calculate stress and strain. [8]

$$\sigma = F/A \quad (1)$$

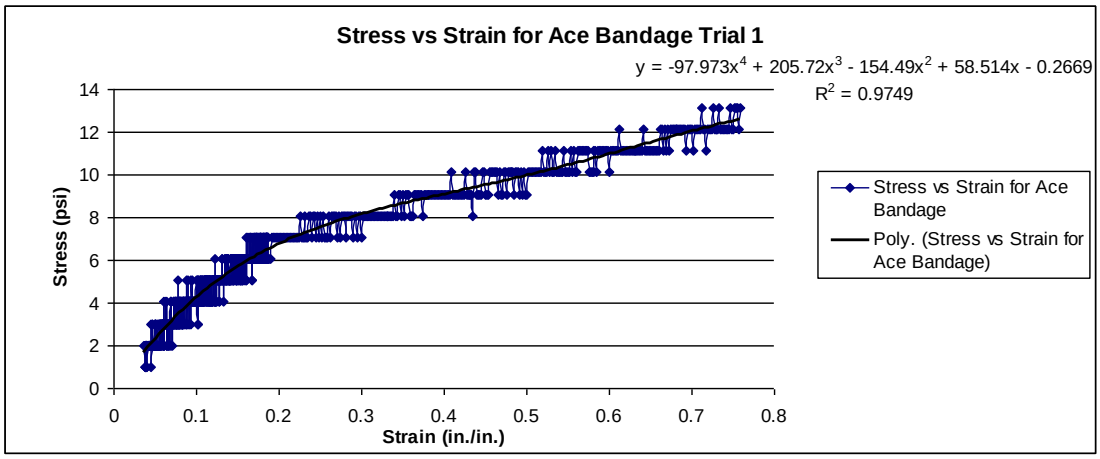
$$\varepsilon = (L_f - L_o)/L_o \quad (2)$$

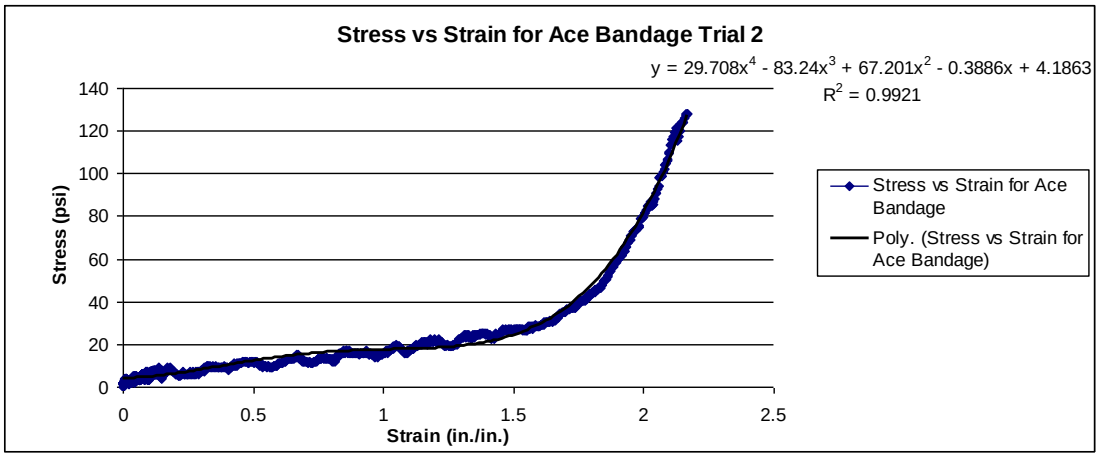
Where:
σ=Stress
F=Force
A=Cross sectional Area

	ACE Bandage	Spandex	Elastic Wrap
Thickness (in.)	0.049	0.022	0.041
Width (in.)	2.019	1.5	2.039
Area (in.*in.)	0.0989	0.0330	0.0836

ε=Strain
L_f=Final Length
L_o=Initial Length

Figure 18: Stress vs Strain with polynomial functions for the ACE bandage for the first, second, and third trial.





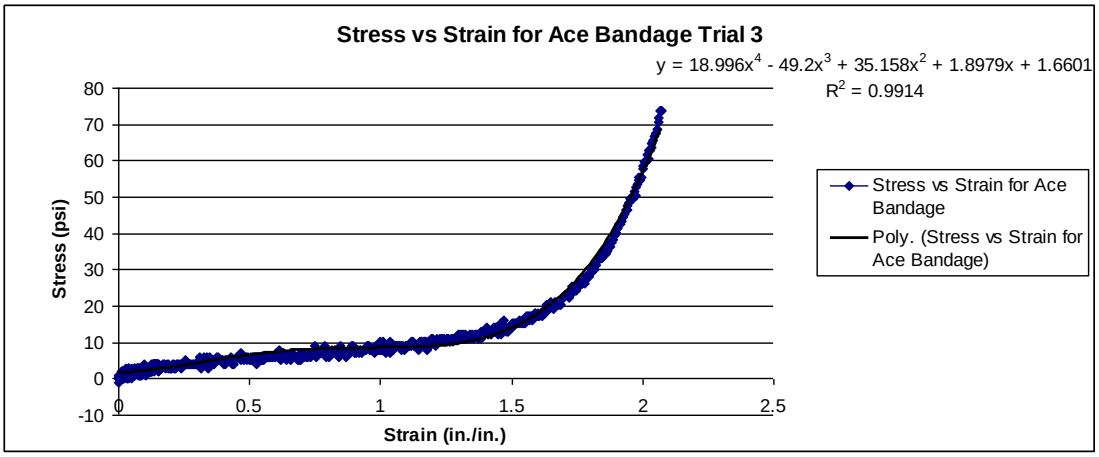
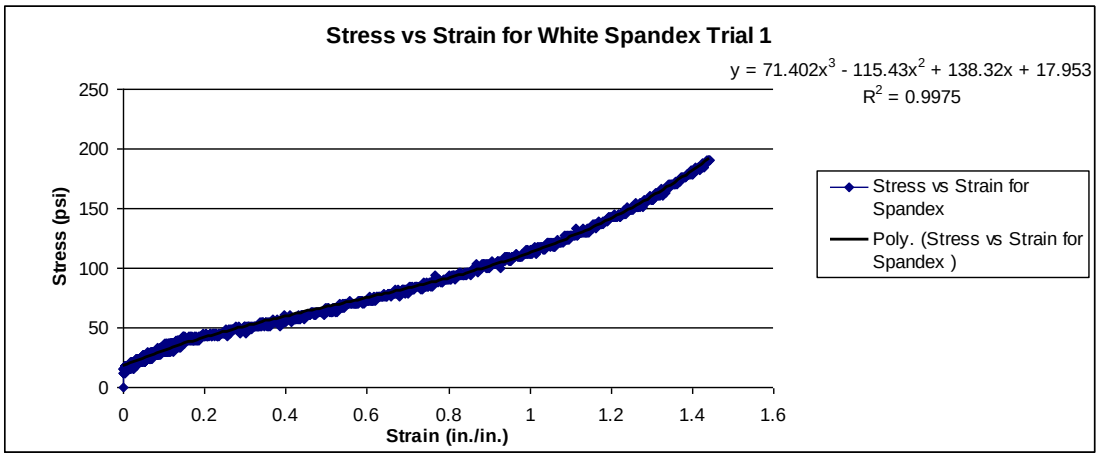
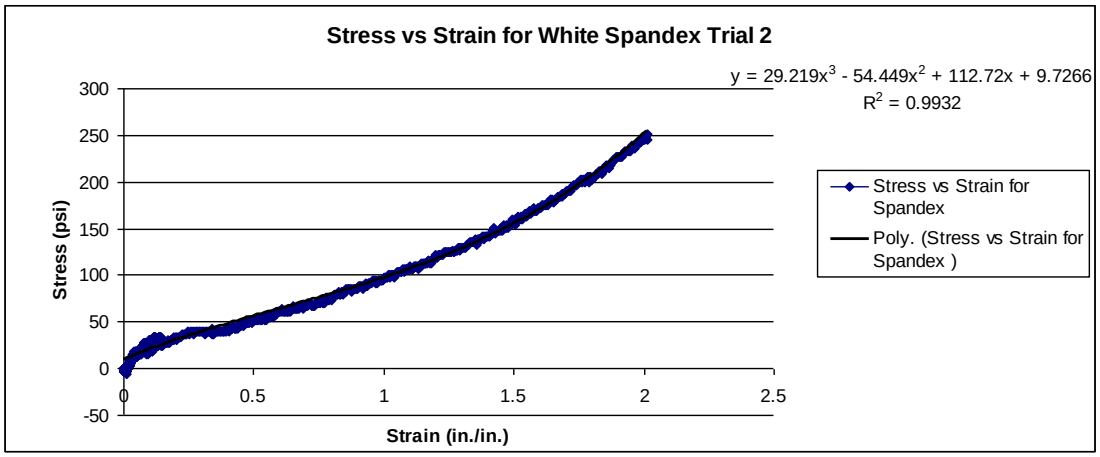


Figure 19: Stress vs Strain with a polynomial function for the spandex for the first, second, and third trial.





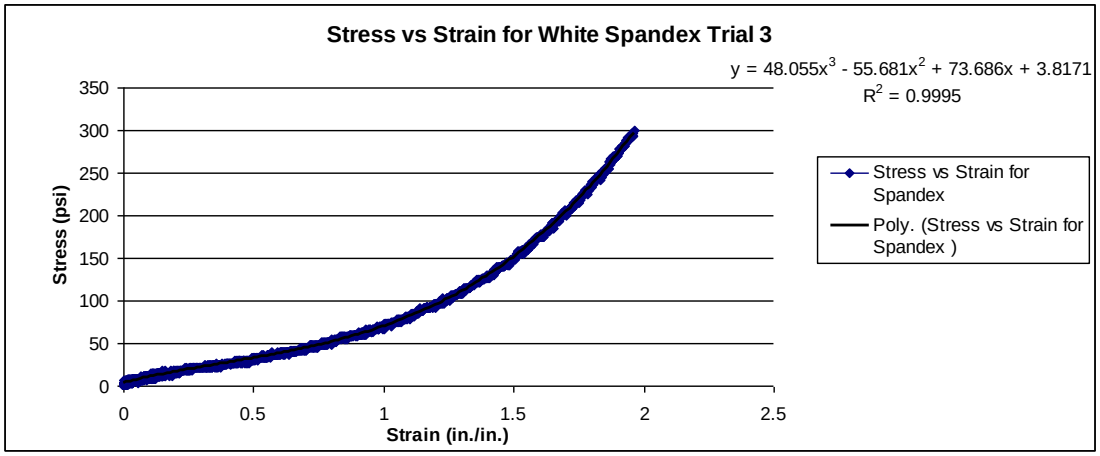
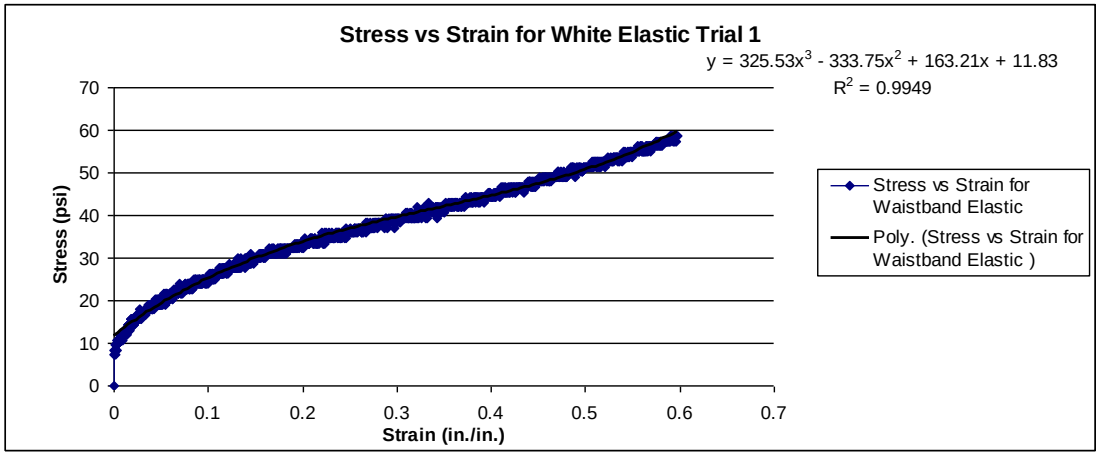
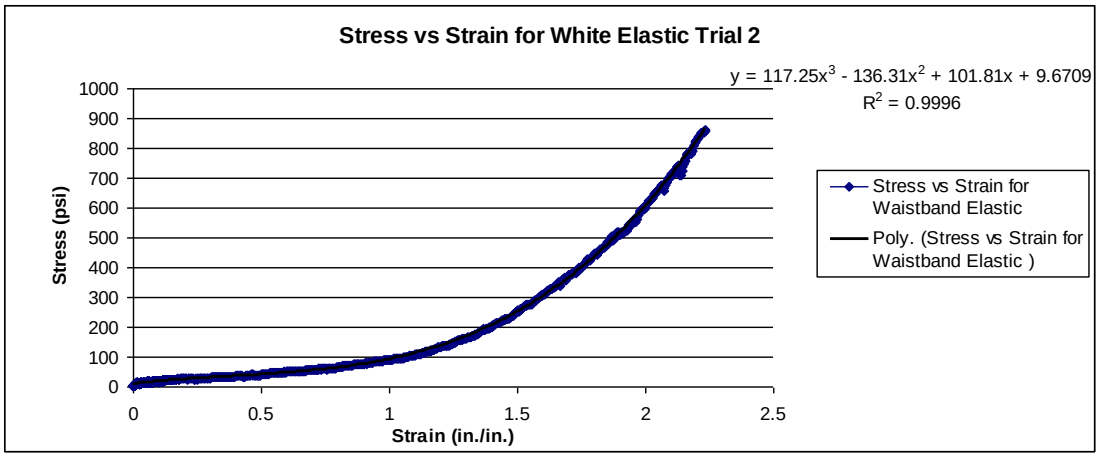


Figure 20: Stress vs Strain with a polynomial function for the white elastic wrap for the first, second, and third trial.





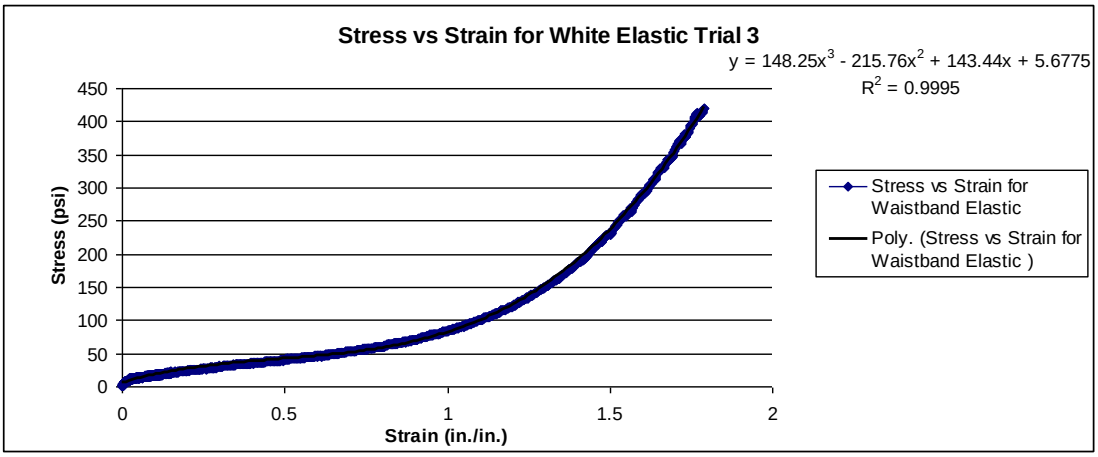


Figure 21: Formula to calculate pressure for Elastic Wrap and Spandex. [8]

$$P = \sigma_{AVG} * t/r \qquad (3)$$

Where:
P=pressure
σ_{AVG}=Average stress
t=thickness of Elastic Wrap or Spandex
r=Radius of Leg

Figure 22: Formula to calculate pressure for ACE Bandage. [8]

Theory of pressure vessel formula for hoop stress:

$$\sigma` = P*r/t \qquad (4)$$

Stress transformation equation:

$$\sigma` = (\sigma_x + \sigma_y)/2 + [(\sigma_x - \sigma_y)/2]*\cos(2\theta) + \tau_{xy}*\sin(2\theta) \qquad (5)$$

Set:
$\sigma_x = \sigma_{AVG}$
$\sigma_y = 0$
$\tau_{xy} = 0$

Eq. (4)=Eq. (5) and solve for P to obtain:

$$P=(t^* \sigma_{AVG}/(2r))^*[1+\cos(2\theta)] \quad (6)$$

Where:
P=pressure
σ`= Stress in hoop direction
t=thickness of ACE bandage time number of layers
r=Radius of Leg
σ_{AVG}=Average stress
θ=angle from plane of diameter of leg to axis of ACE bandage where it is parallel to the gauge length measured positive counterclockwise in degrees
σ`= Stress in hoop direction

Figure 23: Formula to convert psi to mmHg.

$$1 \text{ psi} = 51.7149326 \text{ mmHg} \quad (7)$$

Figure 24: Calculated pressures for ACE Bandage during walking to failure test.

Trial	Initial Length (in.) (gauge length)	Final Length (in.)	Angle (degrees)	Diameter of leg plus ACE bandage at mark location (in.)	Number of total layer of ACE bandage	Strain (in./in.)	Average Pressure applied to leg (psi)	Average Pressure (mmHg)
1	2	3	10.52	21	2	0.500	0.073	3.75
2	2	3.5	0	21	2	0.750	0.114	5.87
3	2	2.75	0	21.5	2	0.375	0.068	3.52
4	2	5	4	20	2	1.500	0.185	9.58
5	2	5	4	20	2	1.500	0.185	9.58
6	3	5	4	20	2	0.667	0.110	5.69

Figure 25: Calculated pressures for prototype made of spandex during walking to failure test.

Trial	Initial Length (in.) (gauge length)	Final Length (in.)	Diameter of leg plus elastic wrap at mark location (in.)	Strain (in./in.)	Average Pressure applied to leg (psi)	Average Pressure (mmHg)
1	2	2.25	20.5	0.125	0.049	2.55
2	3	5	20	0.667	0.141	7.29
3	2	5	20	1.500	0.377	19.49
4	2	5	20	1.500	0.377	19.49
5	2	5	20	1.500	0.377	19.49
6	3	5	20	0.667	0.141	7.29

Figure 26: Calculated pressures for prototype made of elastic wrap during walking to failure test.

Trial	Initial Length (in.) (gauge length)	Final Length (in.)	Diameter of leg plus elastic wrap at mark location (in.)	Strain (in./in.)	Average Pressure applied to leg (psi)	Average Pressure (mmHg)
1	2	2.4	21.5	0.200	0.100	5.19
2	2	2.65	21.5	0.325	0.128	6.63
3	2	5	20	1.500	1.003	51.86
4	2	5	20	1.500	1.003	51.86
5	2	5	20	1.500	1.003	51.86
6	3	5	20	0.667	0.208	10.76

Prototype

Preliminary testing of early generation prototypes was based on a qualitative analysis. Each prototype was worn by 2-3 members of the design team for an extended period of time (typically during an entire day). Each member took notes on different successes and flaws with each prototype. These notes were taken into consideration for the fabrication of the final prototype.

The primary concern involved with testing the final prototype was simulating conditions that the prototype would encounter. The performance of the final prototype would then need to be compared to the performance of the ACE bandage, which would go through identical conditions. It was deemed that the final prototype would be tested in separate trials; the first trial utilizing the prototype by itself and the second trial incorporating the optional belt attachment. Protocol for testing the devices was the following: first the device being tested (ACE bandage, final prototype, or final prototype with belt) was attached to the upper thigh of the tester and the pressure (psi) was determined using the method highlighted below (it was crucial that the

pressure be the same for each device), a mark was drawn on the skin where the top of the device and skin met, the tester then walked approximately 650 steps, and finally performed a set of exercises to simulate activities other than walking. Exercises included 5 horizontal squats, 5 lunges per leg, and touching ones toes 5 times. Data was then recorded pertaining to the areas of interest highlighted Figure 27. Number of steps was determined using a New Balance pedometer. Slip was determined by measuring from the initial mark to the top of the device. Testing then proceeded by walking another 650 steps, performing the exercises, and recording the data. This process continued until the devices slipped one inch or more down the leg or until 10,000 steps were walked without slip of one inch or more. A complete success was deemed as slip of less than one inch following 10,000 steps. A distance of 10,000 steps was determined to be more steps than any individual needing the device would realistically take; thus, if the prototype could achieve this distance it would be able to maintain proper placement for any amount of realistic steps taken by a patient. Failure was determine as slip of one inch before 10,000 steps because at this point it is plausible to assume the dressing would be significantly displaced.

Trial #	Number of Steps	Initial Slip	Exercise completed (yes/no)	Slip after exercise

Figure 27 : Empty table used to record performance of device

Prototype 4 w/out belt				
Trial #	**Number of Steps**	**Initial Slip**	**Exercise completed (yes/no)**	**Slip after exercise**
1	660	0	yes	0
[redacted]	1321	0.125	yes	0.125
	1982	0.125	yes	0.125
	2643	0.25	yes	0.25
	3304	0.25	yes	0.25
	3965	0.25	yes	0.25
	4626	0.25	yes	0.375
	5287	0.375	yes	0.375
	5948	0.375	yes	0.375
	6609	0.375	yes	0.375
	7270	0.375	yes	0.375
	7931	0.375	yes	0.375
	8592	0.375	yes	0.5
	9253	0.5	yes	0.5
	9914	0.5	yes	0.5
	10575	0.5	yes	0.5

Figure 28: Raw data for Prototype 4 without belt testing

ACE Bandage				
Trial #	**Number of Steps**	**Initial Slip**	**Exercise completed (yes/no)**	**Slip after exercise**
1	669	0.375	yes	0.375
[redacted]	1297	0.375	yes	0.375
	1925	0.375	yes	0.375
	2553	0.375	yes	0.375
	3181	0.375	yes	0.5
	3809	0.5	yes	0.625
	4437	0.875	yes	FAIL

Figure 29: Raw data for Ace Bandage testing.

Prototype 4 with belt				
Trial #	**Number of Steps**	**Initial Slip**	**Exercise completed (yes/no)**	**Slip after exercise**
1	0	0	yes	0
[redacted]	675	0	yes	0
	1354	0	yes	0
	2035	0	yes	0
	2710	0	yes	0.125
	3368	0.125	yes	0.125
	4026	0.125	yes	0.125
	4694	0.125	yes	0.125
	5328	0.125	yes	0.125
	6016	0.125	yes	0.125
	6695	0.125	yes	0.25
	7364	0.25	yes	0.25
	8051	0.25	yes	0.25
	8709	0.25	yes	0.25
	9362	0.25	yes	0.25
	10012	0.25	yes	0.25

Figure 30: Raw data for Prototype 4 with belt testing.

Results

Qualitative analyses of comfort and support lead to the conclusion that the pressure which needed to be looked at was .049 psi. As can be seen by figure 31 both the prototype with and without the belt achieved complete success while the ACE bandage failed at approximately 5000 steps.

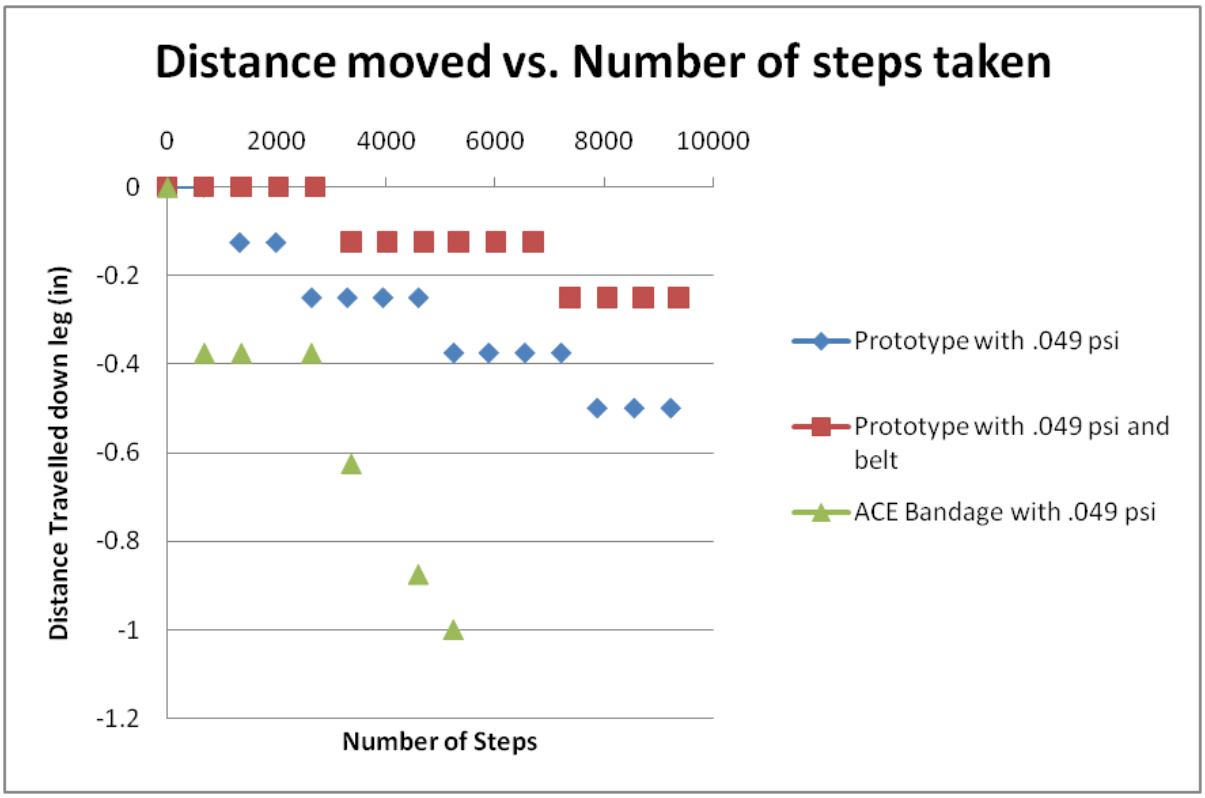


Figure 31: Distance each device moved in reference to the number of steps taken. Each device was placed with a pressure of .049 psi.

Error

Possible sources in methodology are limited, however still exist. The first and primary source of error surrounds the possibility of human error in measuring and recording the distance each device moved down the leg. Due to the relatively small distances being recorded (ie. 1/8") it is possible that some measurements could be flawed. Another source of error comes from the relative deviation between leg sizes. It was hypothesized that the stress/strain analysis allowing for calculated pressure to be ascertained would standardize this methodology and thus limit the error associated with different legs. However, amount of leg hair, relative muscularity of the leg, as well as general shape difference could still cause error. Each device was not tested on the same person due to the limited amount of testing time given for the final prototype and the long duration of time needed for each trial. A final source of error comes from the pedometers utilized to measure the number of steps. In a few preliminary observations of the pedometers the amount of steps were deemed unreasonable. This was due to excessive movement in the steps taken; thus, causing the pedometer to record more steps than actually taken. It was important to keep steps steady to limit this effect.

Semester Time Line

Tasks	January	February				March				April					May
	28	4	11	18	25	4	11	18	25	1	8	15	22	29	6
Research			X	X	X	X									
Brainstorm			X	X	X										
Prototype Design						X	X								
Fabrication								X	X	X	X	X			
Testing										X	X	X	X	X	
Meetings															
Client		X			X										
Team	X	X	X	X	X	X	X		x	X	X	X	X	X	X
Presentation															
Mid- Sem						X									
Final															X
Deliverables															
PDS		X				X									
Peer/Self Evaluation							X								X
Progress Reports	X	X	X	X	X	X	X		x	X	X	X	X	X	X
Mid-Sem Report						X									
Final Report															X
Website	X	X	X	X	X	X	X	X	x	X	X	X	X	X	X

Fig 32. Project Timeline.

Cost Analysis

For testing and the fabrication of four prototypes, the team spent under $300 on supplies. The final prototype cost $13.41 in direct material cost. Given factory discounts on bulk materials, labor costs, and market mark up, this device could feasibly be sold for $40. Both the total project cost and the possible market price coincides with our original goal. Furthermore, due to the fact that there are more than 215,000 split thickness skin grafts per year which would result in $8,600,000 of sales per year within this specific area of interest. This figure could realistically be increased by a significant amount due to the various other applications the device can satisfy. [7]

Ethical Considerations

Due to the fact that this product is meant to be used on human subjects, ethics need to be addressed. The main target market for the final design is going to be post-surgical patients that require surgical dressings to be stabilized. Due to the location of use, the device will therefore be in contact with the skin. The device utilizes two strips of vinyl which will also be in contact with the skin. While vinyl is hypoallergenic for the vast majority of the population, there have been rare instances of allergenic reactions due to this material. If this product is marketed, it will be sold with the knowledge that it has the potential of causing a reaction within this small population. This device could further cause complications if misused and tightened to an excessive degree. To counteract this possibility, the device should be sold with suggested strap tightness based upon strap circumference in relation to the specific patient's leg circumference. Finally it is also important to also note that, in terms of the data collection for testing and design, all volunteers have been and will remain anonymous.

Future Work

Despite the success the group has had with the current prototype, there are areas within the design and testing of the device in which improvement can be made. The first design element in which changes can and should be changed given future work is in the location of the strap attachment which connects the leg device to the belt. Currently the belt attaches with Velcro to the device. This attachment design is not an issue, however the straps attach behind the leg which causes problems. The supportive strap is elastic and as the patient walks this elastic strap is constantly be pulled back and forth. This action does not allow the device to maintain a stable position on the leg but instead causes movement. Any movement of the device has a negative effect as it can bunch up the underlying dressings or work down the leg and out of position. This movement could further cause discomfort for a patient if the fabric were to move back and forth over the wound site. The solution to this problem is to move the attachment location from behind the leg to the side of the leg. This movement would create a more constant distance between the belt and device while walking which in turn would minimize the contraction and relaxation of the elastic strap.

A second area of improvement lies within the manufacturing of the device. Due to the conical shape of the leg, it is necessary for the device to be arched. The degree of this arch and the device size were determined by using the average measurements taken of the leg's profile. However, when the device was sewn together, the predetermined shape tended to change due to the elasticity of the fabric. In order to account for this change either a new method of sewing would need to be utilized or the initial device measurements would need to be exaggerated in order to take this alteration into account.

A final area in which further work could be done is within the testing of the device. The testing of the device and ACE bandage was done through walking and several basic exercises. These exercises did not however take into account all of the movement variables undertaken throughout the course of a normal day. The device could further be tested in the following situations: sitting and standing, movement while sitting, movement while in bed, walking up and down stairs, walking up and down hills. The initial testing was also done while wearing loose boxers and loose athletic shorts.. However, further testing can be done while wearing tight clothing verse loose clothing or while wearing clothing of various fabrics. All of these new tests would need to have methods of standardization in order to create comparable data with the currently used ACE bandage.

Conclusion

Dr. Michael Bentz requested that we devise a new form of bandage stabilizer. After surgery on the thigh, most commonly skin grafting, a patient must keep a proper dressing on the wound for up to six weeks. Currently the only way to hold the dressing in place is with an elastic Ace bandage. This form of bandage does not stay on the wound and slips off of the leg with any sort of motion. It is also very hard to apply to patients while in bed. In order to solve this problem we have came up with an elastic leg wrap. This is a one piece elastic bandage that wraps around the leg and secures against itself using four plastic clips. Our hope is that this new bandage will replace the ACE bandage due to its functionality of not slipping down the leg which will allow patients to have a normal range of motion.

Works Cited

1. Hegde, R., Dahiya, A., Kamath, M., (2004). Nylon Fibers. Retrieved from http://www.engr.utk.edu/mse/Textiles/Nylon%20fibers.htm

2. Prokuski, L. (2002). Negative Pressure Dressings for Open Fracture Wounds. *The Iowa Orthopaedic Journal*, *22*, 20-24. Retrieved from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1888375/

3. Simman, R., Forte, R., Silverberg, B., Moriera-Gonzalez, A., & Williams, F. (2004). Skin Graft With Tie-Over Bolster Dressing vs Negative Pressure: Study. *Wounds*, *16*(2). Retrieved from http://www.medscape.com/viewarticle/470260_2

4. Snow, S. N., & Mikhail, G. R. (Eds.). (2005). *Mohs Micrographic Surgery* (2nd ed., pp. 207-212). Madison, WI: University of Wisconsin Press.

5. Weber, S. M., Ghanem, T. A., & Wax, M. K. (2011, January 4). Skin Grafts, Split-Thickness. *eMedicine Specialties*. Retrieved from http://emedicine.medscape.com/article/876290-overview

6. Wood, B. C., Kirman, C. N., & Molnar, J. A. (2011, January 4). Skin, Grafts. *eMedicine Specialties*. Retrieved from http://emedicine.medscape.com/article/1295109-overview

7. Black, T. (2010, June 9). Wright Medical Launches New Skin Grafting System. In biz journals. (April 29, 2011) http://www.bizjournals.com/memphis/stories/2010/06/07/daily13.htm

8. Hibbeler, R. C. Engineering Mechanics: Mechanics of Materials. Prentice-Hall, Inc., 2010.

Appendix

I. Product Design Specifications

Elastic Bandage Stabilizer (PDS)
5/4/2011

Jay (Baljit) Kler, Taylor Jaraczewski, Lucas Schimmelpfenning, and Cody Bindl

Function: The client, Michael Bentz, has requested a device to replace the current elastic bandage used to hold dressings in place on post operation patients. Current methods for maintaining the dressing's position are ineffective since the current bandage typically slides out of place. The primary location of use for the device is around the upper leg. Additional areas of applications can include the lower leg, the upper arm, and the lower arm.

Client requirements:

- Must hold dressings in place even with normal patient movement.
- Must be easily applied by the patient without external help.
- Cannot create a tourniquet effect on the outer extremities.
- Cannot cause excessive chaffing or rubbing.
- Tension and size should be adjustable for use by various sized patients.

Design requirements:

1. **Physical and Operational Characteristics**
    a. *Performance requirements:*
        i. The device must hold the dressings in initial position.
    b. *Safety:*
        i. The device must be made out of non allergenic materials such as latex.
        ii. The device must not limit blood flow or lymphatic circulation.
        iii. The device must be washable or disposable to prevent infection of the exposed wound.
    c. *Accuracy and Reliability*
        i. The client wants a device that will be effective in 99 percent of the cases.
    d. *Life in Service:*
        i. The device must be usable for 4 to 6 weeks.
    e. *Shelf Life:*
        i. Sterile before use.
        ii. Easily storable.
    f. *Operating Environment:*
        i. Attached to a human limb.

ii. Must be able to accommodate locomotion and be contained under clothing.

g. *Ergonomics:*
   i. Comfortable for patient.
   ii. Must be easy for patient to apply without help.
   iii. Must maintain its position with normal patient movement.

h. *Size:*
   i. Must be able to anchor a dressing in range from 2-15 mm in thickness.
   ii. Must be big enough to cover a 3x4 inch graft.

i. Weight:
   i. Light enough to not fall off from shear weight.

j. *Materials:*
   i. Cotton or nylon is preferable.

k. *Aesthetics, appearance, and finish:*
   i. Function over aesthetics.
   ii. Possibility for future customization (i.e. colorful or themed).

2. Production Characteristics

a. *Quantity:*
   i. At least one proof of concept prototype.
   ii. Eventual varying sizes and lengths for different sized patients.

b. *Target Product Cost:*
   i. Flexible.

3. Miscellaneous

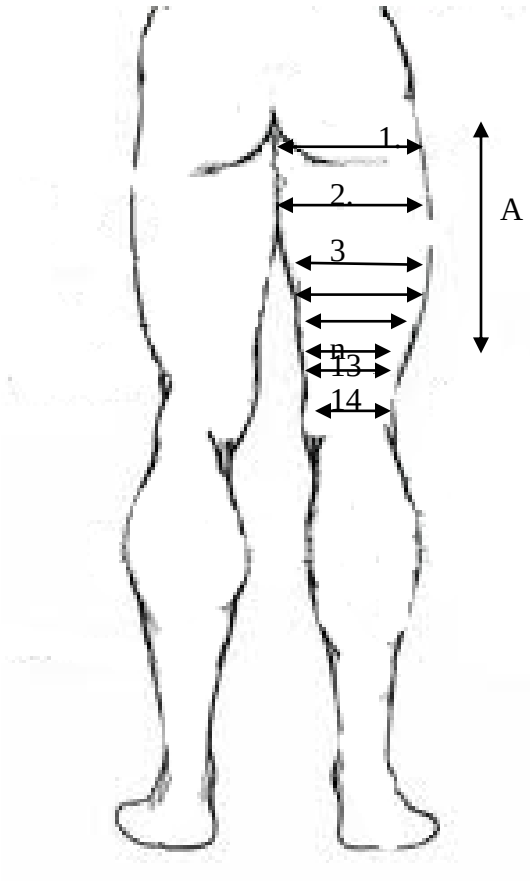
a. *Standards and Specifications:*
   i. Must be non allergenic.
   ii. Must be durable.

b. *Customer:*
   i. Customer wants the ability to easily create a themed and/or colored product to be more appealing towards children.

c. Patient-related concerns:
   i. Must take into account patient allergies.
   ii. Must not create tourniquet effect.

d. *Competition:*
   i. The current protocol for stabilizing dressing is wrapping the wound with Ace bandage tape.

II. Data Analysis Guidelines and Standardization Table



Gender: Male/Female

Age:_____

Height:_____

Weight:_____

Leg Circumference

1_____

2_____

3_____

4_____

5_____

6_____

7_____

8_____

9_____

10_____

11_____

12_____

Knee Circumference

12_____

13_____

14_____

Thigh Length (1-n)

A_____

Measurement Process and Standardizations:

- Measure total height, mass, and gender of subject.
- All measurements should be taken in metric (weight may need conversion)
- All measurements should be taught enough to prevent slack without an impression.
- All circumferential measurements should be taken straight across leg (along horizontal line)
- Determine the highest point along the groin. (1)
- Measure from predetermined point to top of the patella (A)->(1-n)
- Mark five centimeter increments from 1-n.
- Measure circumference at each point with the top of tape at marked point (at point n, use bottom of tape) (1,2,…n)
- Measure at top, middle, and bottom of the patella. (12,13,14)